

REMARKS

The Official Action of November 3, 2005 has been carefully reviewed. In light of the amendments and the following remarks, favorable reconsideration and allowance of the application are respectfully requested.

At the outset, it is noted that the Examiner has made the June 16, 2005 Restriction Requirement final. Accordingly, claims 1-4 have been withdrawn from consideration.

At page 2 of the Official Action, the Examiner asserts that sequence identifiers are missing from page 21, line 21 and page 22, lines 6 and 20. Applicants respectfully submit that the missing sequence identifiers were previously added at the above-identified page and line numbers by the Preliminary Amendment filed on September 16, 2003 with the instant application (see pages 2-4). Indeed, Applicants previously informed the Examiner in the August 16, 2005 response to the Restriction Requirement that proper sequence identifiers were inserted at page 22, lines 7 and 20 in the September 16, 2003 Preliminary Amendment. In light of the foregoing, Applicants respectfully submit that the instant objection is untenable and respectfully request its withdrawal.

The Examiner has also objected to claims 6 and 7 for allegedly starting with an improper article. By the present amendment, the article "A" has been changed to "The" in claims 6 and 7, therefore rendering the instant objection moot.

The Examiner has rejected claims 5-7 for allegedly failing to satisfy the written description and enablement requirements of 35 U.S.C. §112, first paragraph.

At page 5 of the Official Action, claims 5-7 have been rejected under U.S.C. §112, second paragraph, for alleged indefiniteness.

Lastly, claim 5 has been rejected under U.S.C. §102(e) as allegedly anticipated by U.S. Patent 5,877,402, as evidenced by Legen et al. (Plant J. (2002) 31:171-188).

In accordance with the instant amendment, new claims 8 and 9 have been added. Support for new claims 8 and 9 can be found, for example, at page 4, line 32 through page 5, line 1.

The foregoing objections and rejections constitute all of the grounds set forth in the November 3, 2005 Official Action for refusing the present application.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the reasons set forth in this response, Applicants respectfully submit that the 35 U.S.C. §112, first paragraph rejections of claims 5-7; the 35 U.S.C. §112, second paragraph rejections of claims 5-7; and the 35 U.S.C. §102(e) rejection of claim 5, as set forth in the November 3, 2005 Official Action, cannot be maintained. These grounds of rejection are, therefore, respectfully traversed.

Claims 5-7, as Amended, Fully Satisfy the Written Description and Enablement Requirements of 35 U.S.C. §112, First Paragraph:

The Examiner has rejected claims 5-7 for allegedly failing to satisfy the written description and enablement requirements of 35 U.S.C. §112, first paragraph.

With regard to the written description requirement, the Examiner contends that Prrn-114 promoters recited in claims 6 and 7 are not described. Applicants have amended claims 6 and 7 to replace the term "Prrn-114" with Prrn, thereby rendering the instant rejection moot. Support for this amendment can be found, for example, at page 4, line 29.

It is also the Examiner's position that it is not clear that Applicants were in possession of the claimed genus at the

time the instant application was filed because the specification only describes clpP promoters from several organisms; provides a NEP promoter consensus that is present in some, but not all, NEP promoters; and fails to provide PEP consensus sequence.

The Examiner also contends that the instantly rejected claims fail are not fully enabled because while the specification is enabling for certain constructs comprising both NEP and PEP promoters, it allegedly does not provide reasonable enablement for all constructs comprising NEP and PEP.

Applicants respectfully disagree with the Examiner's position. The test for enablement is the balancing of several specifically prescribed factors listed in MPEP § 2164.01(a), as follows:

These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples;

and

- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. **The examiner's analysis must consider all the evidence related to each of these factors**, and any conclusion of nonenablement must be based on the evidence as a whole. (Citation omitted, emphasis supplied.)

Further,

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such

experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.

(MPEP § 2164.01, *emphasis supplied, citations omitted.*)

The instant specification has provided an analysis of both Type I and Type II NEP promoters (see, e.g., page 22). For Type I NEP promoters, an “[a]lignment of the maize clpP, rpoB, and atpB NEP promoters revealed significant homology upstream of the transcription initiation sites” (see page 21, lines 5-8). Furthermore, “maize plastid NEP promoter regions share sequence homology around the transcription initiation site with the conserved CATAGAATA/GAA (SEQ ID No. 63) NEP sequence motif in tobacco” (page 22, lines 4-8). The specification also provides sequences of other DNA sequences flanking the NEP promoter transcription initiation sites, such as atpB promoters from sorghum, barley, wheat and rice, rpoB promoter from rice and clp-111 promoters from rice and wheat (Figure 5B-5D). Type II NEP promoters also have “sequences downstream of the transcription initiation sites” that are “conserved more extensively than upstream” (see page 22, lines 23-26). Conserved sequences from around clpP transcription initiation sites from marchantia, pinus, spinach, tobacco, rice, maize, and arabidopsis are also provided by the specification (Figure 9). Furthermore, Example I of the instant specification also provides methods for identifying NEP promoters. Accordingly, in light of the large number of promoter sequences and partial sequences provided and the extensive direction given for identifying NEP promoters, Applicants respectfully submit that the term “NEP promoter” is fully described and enabled by the instant specification.

Furthermore, Applicants submit that PEP promoters are also fully described and enabled by the instant specification. Indeed, the instant specification at Example IV discloses that the "rbcL gene in rice and maize is transcribed from a PEP promoter (Mullet et al., 1985, *supra*; Nishizawa Y, Hirai A (1987) *Jpn J Genet* 62:389-395)," the "atpB gene in maize chloroplasts is transcribed from a PEP promoter (Mullet et al., 1985, *supra*)," and the "16SrDNA gene (the first gene of the plastid ribosomal RNA operon) in barley chloroplasts is transcribed from a PEP promoter (Reinbothe S, Reibothe C, Heintzen C, Seidenbecher C, Parthier B (1993) *EMBO J* 12:1505-1512)" (page 36, lines 6-26). In addition, the maize and rice PEP promoter in the rrn operon is provided at Figure 17A.

In light of the foregoing, Applicants respectfully submit that the instant rejections under 35 U.S.C. §112, first paragraph are untenable and respectfully request their withdrawal.

Claim 5-7 Satisfy the Requirements of 35 U.S.C. §112, Second Paragraph:

The Examiner has rejected claims 5-7 under 35 U.S.C. §112, second paragraph for alleged indefiniteness on the following three grounds.

First, the Examiner asserts that a "transcription unit" comprises operably linked promoters and that it is unclear where the promoter(s) of the transcription unit are located relative to the promoters in part (b) of claim 5.

Applicants respectfully disagree with the Examiner. The MPEP at §2173.01 states:

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long

as any special meaning assigned to a term is clearly set forth in the specification.

Applicants respectfully submit that the instant specification clearly states that "transcription unit refers to isolated DNA segments which comprise the essential coding regions of one or more exogenous protein(s) of interest" (see page 4, lines 19-22). Transcription units may further comprise "other cis elements for enhancing gene expression, such as enhancer elements" (page 4, lines 22-24). The specification also teaches that such transcription units are "operably linked to the promoters of the invention, such that expression of the transcription unit is regulated by said promoter" (page 4, lines 25-27). Therefore, Applicants respectfully submit that the recitation of the term "transcription unit" in claim 5 is clear.

Second, the Examiner contends that the recitation of "a second PEP promoter" in part (b) of claim 5 is indefinite because there is no first PEP promoter. Applicants have amended claim 5 to replace the term "a second PEP promoter" with "a PEP promoter," thereby rendering the instant rejection moot.

Third, it is the Examiner's position that claim 5 is indefinite for recitation of the phrase "A DNA construct ... comprising ... expression of said transcription unit." Applicants have amended claim 5 to replace item c) with the phrase "wherein expression of said transcription unit is regulated by said promoters." Accordingly, Applicants submit that the instant rejection has been rendered moot.

In view of all of the foregoing, Applicants respectfully request that the instant rejections under 35 U.S.C. §112, second paragraph be withdrawn.

Claim 5 is Not Anticipated by U.S. Patent 5,877,402 as Evidenced by Legen et al. (Plant J. (2002) 31:171-188):

The Examiner has rejected claim 5 under 35 U.S.C. §102(e) as allegedly anticipated by the '402 patent as evidenced by Legen et al. (Plant J. (2002) 31:171-188). It is the Examiner's position that the '402 patent teaches a construct comprising the *rps16* promoter operably linked to the *uidA* coding region and that Legen et al. disclose that the *rps16* promoter comprises NEP and PEP promoters.

Applicants respectfully disagree with the Examiner's analysis of Legen et al. The MPEP at §2131 states:

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such a gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference..." Continental Can Co. USA v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

The Examiner has cited paragraph spanning the columns on page 179 as teaching that the *rps16* promoter comprise NEP and PEP. A review of this paragraph reveals that the *rps16* promoter is cited only in the following sentence:

Remarkably, various genes [i.e. *trnA*(UGC), *trnC*(GCA), ... *rps16*, *rpl23* and *ycf14*(matK), which is assumed to be involved in splicing of certain group II introns], display higher relative transcription rates in wildtype than in the mutant leaf tissue (see Figures 2a and 5a).

Nowhere in this passage is it taught that the *rps16* promoter comprises NEP and PEP promoters. Inasmuch as Legen et al. "must make clear that the missing descriptive matter is necessarily present in the thing described" in the '402 patent, Applicants respectfully submit that the Examiner has failed to set forth a proper rejection under 35 U.S.C. §102(e).

In light of the foregoing, Applicants respectfully request the withdrawal of the instant rejection.

CONCLUSION

In view of the amendments presented herewith and the foregoing remarks, it is respectfully urged that the objections and rejections set forth in the November 3, 2005 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,

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